K113787

510(k) Summary

JAN 4 2013

Date Summary Prepared: December 20, 2011

510(k) Owner Information: Defibtech, LLC
741 Boston Post Road
Guilford, CT 06437

Contact Information: Mr. Ed Horton
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Trade (Proprietary) Name: DDU-120 Fully-Automatic External Defibrillator
Common Name: Automatic External Defibrillator
Classification Name: Automated External Defibrillator (21 CFR 870.5310, Product Code MKJ)

Predicate Device

The DDU-120 is a modification to the DDU-100 predicate device. The design and intended use of the DDU-120 AED is substantially equivalent in performance and safety to the Sentry (DDU-100) AED with Adult and Attenuated Pediatric Pads cleared under the following Proprietary Names:

Proprietary Name	Manufacturer	510(k) Number
Sentry Semi-automatic External Defibrillator, DDP-100 Defibrillation Pads	Defibtech, LLC	K013896
Defibtech AED with Attenuated Defibrillation/Monitoring Pads	Defibtech, LLC	K033896

Device Description

The DDU-120 is a portable, Automated External Defibrillator (AED) intended for use on victims of sudden cardiac arrest (SCA). It is powered by a user-replaceable non-rechargeable battery and supports both adult and pediatric user-replaceable single-use defibrillation/monitoring pads.

The DDU-120 employs a Patient Analysis System that ensures proper pad/patient connection and analyzes the patient's ECG rhythm to determine whether a shock is required. If needed, the DDU-120 delivers a 150 J (50J pediatric) impedance compensated, biphasic truncated exponential defibrillation shock to the patient without user intervention. The cardiac rhythm analysis algorithm and defibrillation energy and waveform utilized are the same as previous Defibtech AEDs.

Voice prompts provide simple instructions for the operator. The DDU-120 AED is capable of recording event information including ECG, audio data and SHOCK/NO SHOCK recommendations.

Intended Use

The DDU-120 AED is indicated for use on victims of sudden cardiac arrest ("SCA") when the patient is:

- Unconscious and unresponsive.
- Not breathing.

For patients under 8 years old, use child/infant electrode pads. Do not delay therapy to determine exact age.

The DDU-120 AED must be used by or on the order of a physician.

Comparison of Technology Characteristics

The DDU-120 AED design characteristics are the same as those of the predicate device. Both devices employ the same underlying scientific technology for patient analysis and defibrillation therapy. Both user interface designs guide the user with voice prompts and visual guidance. DDU-120 is the fully-automatic version of the semi-automatic DDU-100.

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Performance testing

The DDU-120 AED uses similar technologies to provide functionally equivalent performance characteristics as the predicate device. Testing demonstrates that the DDU-120 meets functional and performance specifications. Safety testing assures compliance with applicable industry safety standards.

Conclusion Summary of Safety and Effectiveness

Testing and performance evaluations demonstrate that the Defibtech DDU-120 AED is substantially equivalent to the predicate device. The introduction of the DDU-120 AED does not present new issues of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 4 2013

Defibtech, LLC
c/o Mr. Ed Horton
VP, Quality Assurance & Regulatory Affairs
741 Boston Post Road, Suite 201
Guilford, CT 06437

Re: K113787
Trade/Device Name: DDU -120 Fully Automatic External Defibrillator and Accessories
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: December 20, 2012
Received: December 26, 2012

Dear Mr. Horton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113787

Device Name: DDU-120 Automatic External Defibrillator and Accessories

Indications For Use:

1.3 Indications

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The *DDU-120* AED must be used by or on the order of a physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113787